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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,288	12/19/2001	Jayarama K. Shetty	GC712	8114

7590

05/29/2003

Genencor International, Inc.
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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

6

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/026,288

Applicant(s)

SHETTY ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

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DETAILED ACTION

Claims 1-11 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the recitation "low pH" in claim 1 is indefinite because it is not clear how low, or high, the pH must be to be encompassed by the relative term "low." Also in claim 1, the recitation "suitable for conventional saccharification processes" is indefinite because the criteria for suitability in this context are entirely subjective; what one practitioner considers "suitable" would not necessarily be considered suitable by another practitioner. Similarly, a process considered "conventional" by one practitioner would not necessarily be considered conventional by another.

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The recitation "adversely affect" in claim 2 is also indefinite because it is not clear what would constitute an adverse affect. That is, it is not clear what level of reduction in activity of saccharification enzymes would be encompassed by the claim language.

Because applicant fails to set clear metes and bounds for these claim terms, a holding of indefiniteness under § 112, second paragraph is clearly required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10-136979.

JP '979 discloses an α -amylase from *Bacillus acidocaldarius*, said amylase having all of the claimed functional properties. See English abstract. Moreover, the enzyme must necessarily be able to perform the liquefaction processes recited in the product claims, since the enzyme

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disclosed by JP '979 is the same enzyme as that used in the liquefaction processes disclosed by applicant. A holding of anticipation is clearly required.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Shetty et al ("Factors Affecting the Economics of Glucose Production," Delivering Innovation Through Biotechnology, Genencor International, Inc., (1998)).

As drafted, claim 11 reads on glucose. Shetty clearly discloses that glucose is a known product. A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to

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point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shetty et al ("Factors Affecting the Economics of Glucose Production," Delivering Innovation Through Biotechnology, Genencor International, Inc., (1998)) in view of JP 10-136979.

Shetty discloses a process of preparing glucose from starch, said process using the claimed process parameters. See, e.g. pages 6 and 14. Shetty differs from the claims in that Shetty uses a different α -amylase enzyme than that recited in the claims. However, Shetty discloses that α -amylases active at acidic pH are advantageous in processes of producing glucose from starch. Specifically, the liquefaction step is improved by decreasing chemical demand for pH adjustment, reducing color and by-product formation, and lowering refining requirements and costs (Shetty, page 7). Also, the lower pH afforded by the use of acidophilic α -amylase eliminates the undesirable formation of maltulose (Shetty, page 8). Shetty also discloses that enzymes which do not require calcium or stability are advantageous, as are relatively thermostable enzymes. Shetty, page 11, last sentence. ("It is evident from the above data that an improved

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thermostable alpha-amylase which can operate at a pH below 6.0 and at lower or no calcium will significantly reduce refining costs and improve the final glucose yield.")

As is evident from the English abstract, JP '979 discloses an α -amylase which meets exactly the criteria disclosed by Shetty as being desirable and advantageous for use in the disclosed process of preparing glucose from starch. Specifically, the enzyme is thermostable, acid-stable, optimally active at a pH of about 4, and does not require calcium for activity (see Table 2). Thus, the artisan of ordinary skill practicing Shetty's process clearly would have recognized that the enzyme disclosed by JP '979 possesses all the properties required for use in Shetty's process. The artisan of ordinary skill would therefore clearly have been motivated to have used the enzyme of JP '979 in Shetty's process. A holding of obviousness is therefore required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 10/026,753 in view of Shetty et al ("*Factors Affecting the Economics of Glucose Production*," *Delivering Innovation Through Biotechnology*, Genencor International, Inc., (1998)).

The claims under examination differ from the claims of the '753 application only to the extent that the instant claims recite an additional saccharification step not recited in the claims of the '753 application. However, as is clear from the disclosure in Shetty, the hydrolysis of enzyme-liquefied starch to produce glucose is well known in the art. Thus, the presently claimed addition of saccharification steps to the liquefaction process recited in the claims of the '753 application must be considered an obvious variation of the subject matter recited in the claims of the '753 application.

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This is a provisional obviousness-type double patenting rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
May 21, 2003